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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/049,379  | 02/12/2002  | Houssam Ibrahim      | 2590-35             | 3689             |
| 23117   | 7590        | 06/17/2004           | EXAMINER            |                  |
| NIXON & VANDERHYE, PC<br>1100 N GLEBE ROAD<br>8TH FLOOR<br>ARLINGTON, VA 22201-4714 |             |                      | JOYNES, ROBERT M    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1615                |                  |

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                                |  |
|------------------------------|-------------------------------|--------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/049,379 | Applicant(s)<br>IBRAHIM ET AL. |  |
|                              | Examiner<br>Robert M. Joynes  | Art Unit<br>1615               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of applicants' Response and Amendments filed on January 21, 2004 and February 5, 2004.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ibrahim et al. (US 5716988) in combination with Schilpalius (US 5897871) or Blackshear et al. (US 4439181). Ibrahim teaches a solution of oxaliplatin and water for administration through injection or infusion (Col. 2, lines 9-19). The concentration of the oxaliplatin is from 1 to 5 mg/ml (Col. 2, lines 9-19). The solution can be sealed in a vial infusion pouch, an ampoule or carried in an injection micropump (Col. 2, lines 54-63). The method of preparation is recited in

Example 1 at Col. 3. Ibrahim does not expressly teach the exact concentration for the oxaliplatinum nor does the reference teach other solvents for the solution.

Schlupalius and Blackshear each teach that active agents can be in solution with glycerol and can be administered by injection or infusion (Col. 7, Claims 1-5; and Col. 3, line 15 – Col. 14, line 36, respectively).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a suitable solvent to prepare injection or infusion solution for administration that include oxaliplatinum and glycerol in differing concentrations.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). The Examiner does not see the criticality in the particular concentrations for oxaliplatinum compound. The prior art teaches the compound to have the same activity in a concentration close of the claimed concentration. Any difference is a matter of degree and not of kind.

One of ordinary skill in the art would have been motivated to do this to prepare a pharmaceutically active solution that implements a solution that is non-toxic, is a normal component of human and animal tissues and plasma, and maintains the fluidity of the solution without loss of the biological activity.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to teach or suggest a composition containing oxaliplatinum in solution with one of the recited hydroxylated derivatives. Further, applicants argue there is no motivation to combine the references cited in the Office Action.

It is the position of the Examiner that the prior art teaches parenteral compositions of oxaliplatinum at certain concentrations and that additional components, active or inactive can be added to the solution (Col. 2, line 64 – Col. 3, line2). The secondary references teach known excipients or solvents for parenteral compositions. No criticality is seen in the inclusion of these components or in the claimed concentrations. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of *normal optimization*. The prior art teaches 5mg/mL of oxaliplatinum while the instant claims recite at least 7mg/mL. Both the reference and the instant claims contain oxaliplatinum in water that can also include additional known ingredients for solution composition and that the solution is stable. It is the position of the Examiner that this is part of the normal optimization process for preparing pharmaceutical compositions to vary the active agents concentrations. Again, this a matter of degree and not of kind.

Therefore, the rejections under 35 USC 103 are maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes  
Patent Examiner  
Art Unit 1615

  
**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**